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OFFICE OF PETITIONS

In re Patent No. 7,423,050

Cohen et al.

Issue Date: September 9, 2008

Application No. 10/509,770

Filed: September 28, 2004

Attorney Docket No. 34251-502

NATL.

Title: Pyridinoylpiperidines As

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: DECISION ON REQUEST FOR

: RECONSIDERATION OF

: PATENT TERM ADJUSTMENT

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT", filed November 10, 2008. This matter is being properly treated under 37 CFR 1.705(d) as an application for patent term adjustment.

The application for reconsideration of patent term adjustment is GRANTED-in-Part and Dismissed-in-Part to the extent indicated herein.

The above-identified application matured into U.S. Patent No. 7,423,050 on September 9, 2008. The patent issued with a patent term adjustment of 465 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See, 37 CFR 1.705(d). Patentees request that the patent term adjustment determination for the above-identified patent be changed from 465 days to 656 days.

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under 35 U.S.C. 154 (b) (1) (A) overlaps with a delay under 35 U.S.C. 154 (b) (1) (B) only if the delays occur on the same day. Patentees also state that reductions should have been taken for the supplemental information disclosure statement

(IDS) submitted on May 9, 2008 and a reduction for the submission of a petition filed under 37 CFR 1.48 on August 6, 2008 after the mailing of a Notice of Allowance. Patentees have included the reductions in their calculations.

The petition sets forth a period of adjustment for Office delays totaling 917 days (Three Year Delay under 37 CFR 1.703(b) of 346 days plus a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) of 571 days). Patentee also states that in addition to the 106 days of applicant delay, the Office should have taken an additional reduction of 155(120+35) days for applicants' delay pursuant to 37 CFR 1.704. Thus, patentees assert entitlement to an overall adjustment of 656 days (571 + 191 days for Office delays less 106+155 days for applicants' delays).

Patentees also acknowledge the reduction for applicants' failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704 for 62 days. Patentees state that a reduction for the submission of a supplemental information disclosure statement (IDS) submitted May 9, 2008 required a 79-day reduction because it was submitted after the response to the non-final Office action on February 20, 2008. Thus patentees state an additional 35-day reduction is required as 44 days were taken for the IDS submitted on April 4, 2008. Patentee is correct, pursuant to 37 CFR 1.704(c)(8) a 79 day reduction is required.

Patentees also state a reduction for the submission of a petition under 37 CFR 1.48 after payment of the issue fee is required. Patentees' own calculation of the period of reduction in connection with the submission under 37 CFR 1.312, filed August 6, 2008, incorrectly sets forth a reduction of 120 days. The correct reduction in this regard is 35 days. See, 37 CFR 1.704(c)(10)(ii). Thus the total reduction for applicant delay is 176 days (62+79+35). The petition is GRANTED to the extent indicated that Patentees acknowledge that additional reductions based on 1.704 (c)(8) and (c)(10) were required.

The Office finds the following: under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704.

The Office agrees that because certain actions were not taken within specified time frames, the patent is entitled to an adjustment of 571 days pursuant to 37 CFR 1.702(a). It should be noted that the calculation of any over three year delay for an application filed pursuant to 35 USC 371 is calculated based upon the commencement date. In this instance the commencement date of the application was September 29, 2004. Thus, the application was pending three years and 346 days until the issuance of the patent on September 9, 2008.

At issue is whether patentees should accrue an additional 346 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 571 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 346 days overlap. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See, 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See, Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See, also, Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See, also, Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing or commencement date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing or commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application commenced, September 29, 2004, to the date the patent issued on September 9, 2008. Prior to the issuance of the patent, 571 days of patent term adjustment were accorded for

The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

the Office failing to respond within specified time frames during the pendency of the application. The 571 days accorded pursuant to 37 CFR 1.702(a) overlap with the 346 days of Office delay under 37 CFR 1.702(b).

The Office did not delay 571 days and then delay an additional 346 days. Accordingly, 571 days of patent term adjustment (not 571 days and 346 days) was properly entered because the period of delay of 346 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 571 days attributable to grounds specified in § 1.702(a). Entry of both periods is not warranted. Thus, 571 days, which includes the 346 days pursuant to 37 CFR 1.702(a), is determined to be the actual number of days that the issuance of the patent was delayed.

Accordingly, at issuance, the Office properly entered an overall adjustment of 571 days of patent term adjustment for the Office taking in excess of three years to issue the patent. Patentees' request for extension or adjustment based on over three-year delay is Dismissed.

In view thereof, the patent term adjustment indicated in the patent should have been three hundred ninety-five (395) days (571 - 62-79-35).

Receipt of the \$200.00 fee set forth in 37 CFR 1.18(e) is acknowledged. No additional fees are required.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond to this decision. No extensions of time will be granted under § 1.136.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. See 35 U.S.C. § 254 and 37 CFR § 1.322. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by three hundred ninety-five (395) days.

Telephone inquiries specific to this matter should be directed to Petitions Attorney Charlema Grant, at (571) 272-3215.

Kery Fries
Senior Legal Advisor Attorney
Office of Patent Legal Administration

Enclosure: Copy of DRAFT Certificate of Correction



UNITED STATES PATENT AND TRADEMARK OFFICE **CERTIFICATE OF CORRECTION**

PATENT

: 7,423,050 B2

DATED

: September 9, 2008

INVENTOR(S): Michael Philip Cohen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (465) days

Delete the phrase "by 465 days" and insert – by 395 days--

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